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Appendix 8 – Summary of Safety and Effectiveness

CareFusion
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
PHONE: 847.578.5829
FAX: 847.578.2361

DEC 2 3 2009

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
As required by section 807.92(c)
V.Mueller Camera Controller with Storage Cart

Sponsor:	CareFusion 1500 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact:	Gina Rajterowski
Telephone:	(847) 578-5829
Fax:	(847) 578-2361
Date Summary Prepared:	November 2009
Device Name	V.Mueller Camera Controller with Storage Cart
Common Name	Endoscope Holder
Classification Name	Endoscope Holder (21 CFR, 876.1500, Product Code OCV)
Predicate Device(s)	Statarius Endoscope Holder, K061292

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Description:	The V.Mueller Camera Controller with Storage Cart is a manually operated, mechanical surgical device. The instrument provides for the one handed control for the positioning/repositioning of an endoscope during surgical procedures. The V.Mueller Camera Controller eliminates the need for the surgeon or assistant to continuously hold the endoscope during surgical procedures. The system includes a storage cart to be used for setup, storage, and transport of the device.
Intended Use:	The V. Mueller® Camera Controller is intended for use by surgeons for holding rigid endoscopes with diameters from 5 - 10 mm during diagnostic and therapeutic surgical procedures. The system includes a storage cart to be used for setup, storage, and transport of the device.
Summary of Technological Characteristics:	The proposed device and the predicate devices are composed of the same or similar principals of operation, design, materials and manufacturing characteristics.
Summary of Testing:	The V.Mueller Camera Controller with Storage Cart was evaluated in non-clinical tests under various conditions to assess the design performance and conformance to design specifications.
Non-Clinical Testing	Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed predicate device with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 23 2009

Ms. Gina Rajterowski
Regulatory Affairs Manager
CareFusion, 2200
1500 Waukegan Road
WAUKEGAN IL 60085

Re: K093616
Trade/Device Name: V.Mueller Camera Controller with Storage Cart
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCV
Dated: November 3, 2009
Received: November 19, 2009

Dear Ms. Rajterowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CareFusion

CareFusion
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
PHONE: 847.578.5829
FAX: 847.578.2361

Indication for Use

510(k) Number (if known): K093616

Device Name: V.Mueller Camera Controller With Storage Cart

Indications For Use:

The V. Mueller® Camera Controller is intended for use by surgeons for holding rigid endoscopes with diameters from 5 - 10 mm during diagnostic and therapeutic surgical procedures. The system includes a storage cart to be used for setup, storage, and transport of the device.

Prescription Use _X_ or Over-The Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093616